IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: Garcia-Rodenas et al.
Appl. No.: 10/562,243
Conf. No.: 6067
Filed: December 22, 2005
Title: NUTRITIONAL FORMULA FOR OPTIMAL GUT BARRIER
Art Unit: 1645
Examiner: B. Gangle
Docket No.: 3712036-00694

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

RENEWED PETITION UNDER 37 CFR 1.137(b)

Dear Examiner:

Pursuant to 37 CFR 1.137(b), the Applicant, through his undersigned attorney, hereby submits this Renewed Petition to Revive the above-referenced patent application in view of the Notice of Improper Request for Continued Examination dated October 27, 2009 (actually sent on October 26, 2009) and the Decision on Petition dated March 30, 2010. A copy of the Notice of Improper Request for Continued Examination is attached hereto at Exhibit B, and a copy of the Decision on Petition is attached hereto as Exhibit C.

Applicant hereby states that the entire delay in filing the required reply from the due date for the reply until the filing of a grantable petition pursuant to 37 CFR 1.137(b) was unintentional.

The Response to Office Action mailed on April 17, 2009 is submitted herewith, which was improperly omitted from the filing of the Request for Continued Examination filed on October 19, 2009. Per the telephone conversation between Applicant's representative and Examiner Brian Gangle on April 29, 2010, Applicant submits that, in view of the resubmission of the Response and below-mentioned documents, and the previous submission of the Request for Continued Examination, the Renewed Petition comprises a proper response to the Office Action mailed on April 17, 2009. Accordingly, Applicant respectfully requests that the Decision

on Petition mailed March 30, 2010 be reconsidered and withdrawn, and that the Renewed Petition under 37 CFR 1.137(b) be granted.

In accordance with the Manual for Patent Examining Procedure ("MPEP") Section 711.02 and 37 CFR 1.137(b), this Renewed Petition includes:

1. Renewed Petition to Revive Under 37 CFR 1.137 (b) (Exhibit A);
2. The Notice of Improper Request for Continued Examination (Exhibit B);
3. The Decision on Petition mailed March 30, 2010 (Exhibit C);
4. The Response to the Final Office Action mailed April 17, 2009 (Exhibit D);
5. A statement that the entire delay in filing the required reply from the due date for the reply until the filing of a grantable petition pursuant to 37 CFR 1.137(b) was unintentional (see above); and
6. The petition fee as set forth in 37 CFR 1.17(m) (previously authorized).

Please note that this Renewed Petition does not include a Terminal Disclaimer under 37 CFR 1.137(d) because the present application is not (1) a design application, (2) a utility application filed before June 8, 1995, or (3) a plant application filed before June 8, 1995.

The Director was previously authorized to charge $1,620.00 for the Petition to Revive (unintentional) fee pursuant to 37 CFR 1.17(m). The Director is authorized to charge any additional fees which may be required, or to credit any overpayment to Deposit Account No. 02-1818. If such a withdrawal is made, please indicate the Attorney Docket No. 3712036-00694 on the account statement.

Respectfully submitted,

K&L GATES LLP

BY _____

Robert M. Barrett
Reg. No. 30,142
Customer No. 29157
Phone No. 312-807-4441

Dated: April 30, 2010

EXHIBIT A

Doc Code: PET.OP

Document Description: Petition for Review by the Office of Petitions

PTO/SB/64 (07-09)
Approved for use through 07/31/2012. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

PETITION FOR REVIVAL OF AN APPLICATION FOR PATENT ABANDONED UNINTENTIONALLY UNDER 37 CFR 1.137(b)	Docket Number (Optional) 3712036-00694

First named inventor: Garcia-Rodenas et al.

Application No.: 10/562,243 Art Unit: 1645

Filed: December 22, 2005 Examiner: B. Gangle

Title: NUTRITIONAL FORMULA FOR OPTIMAL GUT BARRIER

Attention: Office of Petitions
Mail Stop Petition
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450
FAX (571) 273-8300

NOTE: If information or assistance is needed in completing this form, please contact Petitions Information at (571) 272-3282.

The above-identified application became abandoned for failure to file a timely and proper reply to a notice or action by the United States Patent and Trademark Office. The date of abandonment is the day after the expiration date of the period set for reply in the office notice or action plus any extensions of time actually obtained.

APPLICANT HEREBY PETITIONS FOR REVIVAL OF THIS APPLICATION

NOTE: A grantable petition requires the following items:
(1) Petition fee;
(2) Reply and/or issue fee;
(3) Terminal disclaimer with disclaimer fee - required for all utility and plant applications filed before June 8, 1995; and for all design applications; and
(4) Statement that the entire delay was unintentional

1. Petition Fee

☐ Small entity-fee $ _____ (37 CFR 1.17(m)). Application claims small entity status. See 37 CFR 1.27.

☑ Other than small entity-fee $ 1620.00 (37 CFR 1.17(m))

2. Reply and/or fee

A. The reply and/or fee to the above-noted Office action in the form of Response to Final Office Action (identify type of reply):

☐ has been filed previously on _____.

☑ is enclosed herewith.

B. The issue fee and publication fee (if applicable) of $_____.

☐ has been paid previously on _____.

☐ is enclosed herewith.

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.

3. Terminal disclaimer with disclaimer fee

☑ Since this utility/plant application was filed on or after June 8, 1995, no terminal disclaimer is required.

☐ A terminal disclaimer (and disclaimer fee (37 CFR 1.20(d)) of $_____for a small entity or $_____ for other than a small entity) disclaiming the required period of time is enclosed herewith (see PTO/SB/63).

4. STATEMENT: The entire delay in filing the required reply from the due date for the required reply until the filing of a grantable petition under 37 CFR 1.137(b) was unintentional. [NOTE: The United States Patent and Trademark Office may require additional information if there is a question as to whether either the abandonment or the delay in filing a petition under 37 CFR 1.137(b) was unintentional (MPEP 711.03(c), subsections (III)(C) and (D)).]

WARNING:

Petitioner/applicant is cautioned to avoid submitting personal information in documents filed in a patent application that may contribute to identity theft. Personal information such as social security numbers, bank account numbers, or credit card numbers (other than a check or credit card authorization form PTO-2038 submitted for payment purposes) is never required by the USPTO to support a petition or an application. If this type of personal information is included in documents submitted to the USPTO, petitioners/applicants should consider redacting such personal information from the documents before submitting them to the USPTO. Petitioner/applicant is advised that the record of a patent application is available to the public after publication of the application (unless a non-publication request in compliance with 37 CFR 1.213(a) is made in the application) or issuance of a patent. Furthermore, the record from an abandoned application may also be available to the public if the application is referenced in a published application or an issued patent (see 37 CFR 1.14). Checks and credit card authorization forms PTO-2038 submitted for payment purposes are not retained in the application file and therefore are ~~not publicly~~ available.

_____ Signature	April 30, 2010 Date
Robert M. Barrett Type or Printed name	30,142 Registration Number, If applicable
P.O. Box 1135 Address	312-807-4204 Telephone Number
Chicago, Illinois 60690-1135 Address	

Enclosures:

☑ Fee Payment

☑ Reply

☐ Terminal Disclaimer Form

☐ Additional sheets containing statements establishing unintentional delay

☑ Other: Exhibits A-D

CERTIFICATE OF MAILING OR TRANSMISSION [37 CFR 1.8(a)]

I hereby certify that this correspondence is being:

☐ Deposited with the United States Postal Service on the date shown below with sufficient postage as first class mail in an envelope addressed to: Mail Stop Petition, Commissioner for Patents, P. O. Box 1450, Alexandria, VA 22313-1450.

☐ Transmitted by facsimile on the date shown below to the United States Patent and Trademark Office at (571) 273-8300.

_____ Date	_____ Signature
	_____ Typed or printed name of person signing certificate

Privacy Act Statement

The **Privacy Act of 1974 (P.L. 93-579)** requires that you be given certain information in connection with your submission of the attached form related to a patent application or patent. Accordingly, pursuant to the requirements of the Act, please be advised that: (1) the general authority for the collection of this information is 35 U.S.C. 2(b)(2); (2) furnishing of the information solicited is voluntary; and (3) the principal purpose for which the information is used by the U.S. Patent and Trademark Office is to process and/or examine your submission related to a patent application or patent. If you do not furnish the requested information, the U.S. Patent and Trademark Office may not be able to process and/or examine your submission, which may result in termination of proceedings or abandonment of the application or expiration of the patent.

The information provided by you in this form will be subject to the following routine uses:

1. The information on this form will be treated confidentially to the extent allowed under the Freedom of Information Act (5 U.S.C. 552) and the Privacy Act (5 U.S.C. 552a). Records from this system of records may be disclosed to the Department of Justice to determine whether the Freedom of Information Act requires disclosure of these records.
2. A record from this system of records may be disclosed, as a routine use, in the course of presenting evidence to a court, magistrate, or administrative tribunal, including disclosures to opposing counsel in the course of settlement negotiations.
3. A record in this system of records may be disclosed, as a routine use, to a Member of Congress submitting a request involving an individual, to whom the record pertains, when the individual has requested assistance from the Member with respect to the subject matter of the record.
4. A record in this system of records may be disclosed, as a routine use, to a contractor of the Agency having need for the information in order to perform a contract. Recipients of information shall be required to comply with the requirements of the Privacy Act of 1974, as amended, pursuant to 5 U.S.C. 552a(m).
5. A record related to an International Application filed under the Patent Cooperation Treaty in this system of records may be disclosed, as a routine use, to the International Bureau of the World Intellectual Property Organization, pursuant to the Patent Cooperation Treaty.
6. A record in this system of records may be disclosed, as a routine use, to another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)).
7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (i.e., GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.
8. A record from this system of records may be disclosed, as a routine use, to the public after either publication of the application pursuant to 35 U.S.C. 122(b) or issuance of a patent pursuant to 35 U.S.C. 151. Further, a record may be disclosed, subject to the limitations of 37 CFR 1.14, as a routine use, to the public if the record was filed in an application which became abandoned or in which the proceedings were terminated and which application is referenced by either a published application, an application open to public inspections or an issued patent.
9. A record from this system of records may be disclosed, as a routine use, to a Federal, State, or local law enforcement agency, if the USPTO becomes aware of a violation or potential violation of law or regulation.

EXHIBIT B

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
U.S. Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

29157 e 10/27/2009

K&L Gates LLP
P.O. Box 1135
CHICAGO, IL 60690

Paper No.

Application No.:	**10/562,243**	**Date Mailed:**	**10/27/2009**
First Named Inventor:	Garcia-Rodenas, Clara, Lucia	Examiner:	GANGLE, BRIAN J
Attorney Docket No.:	112701-694	Art Unit:	1645
Confirmation No.:	6067	Filing Date:	12/22/2005

Please find attached an Office communication concerning this application or proceeding.

Commissioner for Patents

NOTICE OF IMPROPER REQUEST FOR CONTINUED EXAMINATION (RCE)	Application No. 10/562,243	Applicant(s) GARCIA-RODENAS ET AL.	
		Art Unit 1624	Date Mailed:

The request for continued examination (RCE) under 37 CFR 1.114 filed on 19 October, 2009 is improper for reason(s) indicated below:

1. ☐ Continued examination under 37 CFR 1.114 does not apply to an application for a design patent. Applicant may wish to consider filing a continuing application under 37 CFR 1.53(b) or a CPA under 37 CFR 1.53(d). An RCE cannot be treated as a CPA.

2. ☐ Continued examination under 37 CFR 1.114 does not apply to an application that was filed before June 8, 1995. Applicant may wish to consider filing a continuing application under 37 CFR 1.53(b).

3. ☐ Continued examination under 37 CFR 1.114 does not apply to an application unless prosecution in the application is closed. If the RCE was accompanied by a reply to a non-final Office action, the reply will be entered and considered under 37 CFR 1.111. If the RCE was not accompanied by a reply, the time period set forth in the last Office action continues to run from the mailing date of that action.

4. ☐ The request was not filed before payment of the issue fee, and no petition under 37 CFR 1.313 was granted. If this application has not yet issued as a patent, applicant may wish to consider filing either a petition under 37 CFR 1.313 to withdraw this application from issue, or a continuing application under 37 CFR 1.53(b).

5. ☐ The request was not filed before abandonment of the application. The application was abandoned, or proceedings terminated on _____. Applicant may wish to consider filing a petition under 37 CFR 1.137 to revive this abandoned application.

6. ☐ The request was not accompanied by the fee set forth in 37 CFR 1.17(e) as required by 37 CFR 1.114. Since the application is not under appeal, the time period set forth in the final Office action or notice of allowance continues to run from the mailing date of that action or notice.

7. ☒ The request was not accompanied by a submission as required by 37 CFR 1.114. Since theapplication is not under appeal, the time period set forth in the final Office action or notice of allowance continues to run from the mailing date of that action or notice.

Note: A continued prosecution application (CPA) under 37 CFR 1.53(d) cannot be filed in a utility or plant application. A CPA filed in a utility or plant application that has a filing date **on or after June 8, 1995** will be treated as an RCE under 37 CFR 1.114. The request for a CPA in the instant application, however, has been treated as an improper RCE for the reason(s) indicated above.

A copy of this Notice MUST be returned with the reply.

Direct any questions concerning this notice to

/PAUL M. STANBACK/, Technology Center 1600

Telephone Number: 571-272-0675

EXHIBIT C

UNITED STATES PATENT AND TRADEMARK OFFICE

Commissioner for Patents
United States Patent and Trademark Office
P.O. Box 1450
Alexandria, VA 22313-1450
www.uspto.gov

K&L Gates LLP
P.O. Box 1135
CHICAGO IL 60690

MAILED

MAR 3 0 2010

OFFICE OF PETITIONS

In re Application of :
Clara L. GARCIA-RODENAS et al. :
Application No. 10/562,243 : DECISION ON PETITION
Filed: December 22, 2005 :
Attorney Docket No. **3712036.00694** :

This is a decision on the petition under the unintentional provisions of 37 CFR 1.137(b), filed October 27, 2009, to revive the above-identified application.

The petition is **DISMISSED**.

Any request for reconsideration of this decision must be submitted within TWO (2) MONTHS from the mail date of this decision. Extensions of time under 37 CFR 1.136(a) are permitted. The reconsideration request should include a cover letter entitled "Renewed Petition under 37 CFR 1.137(b)." This is **not** a final agency action within the meaning of 5 U.S.C. § 704.

The application became abandoned for failure to timely reply within the meaning of 37 CFR 1.113 to the final Office action, mailed April 17, 2009, which set a shortened statutory period for reply of three (3) months. A three (3) months extension of time under the provisions of 37 CFR 1.136(a) was obtained. Accordingly, the application became abandoned on October 20, 2009.

A grantable petition under 37 CFR 1.137(b) must be accompanied by: (1) the required reply, unless previously filed; (2) the petition fee as set forth in 37 CFR 1.17(m); (3) a statement that the entire delay in filing the required reply from the due date for the reply until the filing of a grantable petition pursuant to 37 CFR 1.137(b) was unintentional; and (4) any terminal disclaimer (and fee as set forth in 37 CFR 1.20(d)) required by 37 CFR 1.137(d). Where there is a question as to whether either the abandonment or the delay in filing a petition under 37 CFR 1.137 was unintentional, the Director may require additional information. See MPEP 711.03(c)(II)(C) and (D). The instant petition lacks item(s) (1).

Petitioner failed to provide an amendment that prima *facie places* the application in condition for allowance. See attached courtesy copy of examiner's advisory action.

Further correspondence with respect to this matter should be addressed as follows:

By Mail: Mail Stop PETITION
Commissioner for Patents
P. O. Box 1450
Alexandria, VA 22313-1450

By hand: U. S. Patent and Trademark Office
Customer Service Window, Mail Stop Petitions
Randolph Building
401 Dulany Street
Alexandria, VA 22314

The centralized facsimile number is **(571) 273-8300.**

Telephone inquiries concerning this decision should be directed to Tredelle Jackson at (571) 272-2783.

Ramesh Krishnamurthy
Petitions Examiner
Office of Petitions

Please see attached PTOL-303

Advisory Action Before the Filing of an Appeal Brief	**Application No.**	**Applicant(s)**	
	10/562,243	GARCIA-RODENAS ET AL.	
	Examiner	**Art Unit**	
	Brian J. Gangle	1645	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 27 October 2009 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☒ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:
   a) ☒ The period for reply expires 3 months from the mailing date of the final rejection.
   b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

   Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

NOTICE OF APPEAL

2. ☐ The Notice of Appeal was filed on _____. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

AMENDMENTS

3. ☒ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because
   (a) ☒ They raise new issues that would require further consideration and/or search (see NOTE below);
   (b) ☒ They raise the issue of new matter (see NOTE below);
   (c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
   (d) ☐ They present additional claims without cancèling a corresponding number of finally rejected claims.

   NOTE: *See Continuation Sheet*. (See 37 CFR 1.116 and 41.33(a)).
4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).
5. ☐ Applicant's reply has overcome the following rejection(s): _____.
6. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
7. ☒ For purposes of appeal, the proposed amendment(s): a) ☒ will not be entered, or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.
   The status of the claim(s) is (or will be) as follows:
   Claim(s) allowed: _____.
   Claim(s) objected to: _____.
   Claim(s) rejected: *11,17 and 18*.
   Claim(s) withdrawn from consideration: *1-10,12,13,15,16,19 and 20*.

AFFIDAVIT OR OTHER EVIDENCE

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).
9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing a good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).
10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

REQUEST FOR RECONSIDERATION/OTHER

11. ☐ The request for reconsideration has been considered but does NOT place the application in condition for allowance because: _____.
12. ☐ Note the attached Information *Disclosure Statement*(s). (PTO/SB/08) Paper No(s). _____
13. ☐ Other: _____.

/Robert B Mondesi/
Supervisory Patent Examiner, Art Unit 1645

Continuation of 3. NOTE: The new limitations added to claim 11 raise new matter issues as well as requiring a new search.

EXHIBIT D

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants:	Garcia-Rodenas et al.
Appl. No.:	10/562,243
Conf. No.:	6067
Filed:	December 22, 2005
Title:	NUTRITIONAL FORMULA FOR OPTIMAL GUT BARRIER
Art Unit:	1645
Examiner:	B. Gangle
Docket No.:	3712036-00694

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

AMENDMENT

Examiner:

In response to the final Office Action dated April 17, 2009, please amend the above-identified patent application as follows:

Amendments to the Claims are reflected in the listing of claims which begins on page 2 of this paper.

Remarks begin on page 6 of this paper.

Amendments to the Claims:

This listing of claims will replace all prior versions, and listings, of claims in the application:

Listing of Claims:

Claim 1 (withdrawn): A nutritional composition comprising a combination of a least one substance selected from the group consisting of specific fats and non-digestible oligosaccharides, associated with at least one microorganism, in an amount effective to induce a pattern of gut barrier maturation similar to that observed with breast-feeding.

Claim 2 (withdrawn): A nutritional composition according to claim 1, comprising an effective amount of composition to ensure an optimal barrier function in infants and/or maintaining gut barrier homeostasis.

Claim 3 (withdrawn): A composition according to claim 1, wherein said microorganism is selected from the group consisting of Lactobacilli, Bifidobacteria, Streptococci, Pediococci, Enterococci, Lactococci, Oenococci, Staphylococci, Bacteroides, yeasts and mixtures thereof.

Claim 4 (withdrawn): A composition according to claim 1, wherein the microorganism is selected from the group consisting of Bifidobacterium CNCM I-2170, Bifidobacterium CNCM I-2168, Bifidobacterium CNCM I-2169, Lactobacillus johnsonii CNCM I-1225, Lactobacillus paracasei CNCM I-2116, Bifidobacterium lactis ATCC 27536, Bifidobacterium longum BB536 and mixtures thereof.

Claim 5 (withdrawn): A composition according to claim 1, wherein the non digestible oligosaccharides are selected from the group consisting of fructo-oligosaccharides, galacto-oligosaccharides, sialo-olilgosaccharides, xylo-oligosaccharides, inulin, arabic gum, guar gum, resistant starch and milk-derived oligosaccharides.

Claim 6 (withdrawn): A composition according to claim 1, wherein the specific fats are selected from the group consisting of lipids LC-PUFA, and gangliosides.

Claim 7 (withdrawn): A composition according to claim 1, wherein the composition is ingestible carrier or support.

Claim 8 (withdrawn): A composition according to claim 1, wherein the composition is in a form selected from the group consisting of a complete diet, a supplement and a medicament.

Claim 9 (withdrawn): A composition according to claim 1, wherein the composition is in a form selected from the group consisting of a low birth weight, a starter or a follow-up infant formula and a baby food.

Claim 10 (withdrawn): A method for maintaining gut barrier homeostatis comprising the steps of administering a combination of a least one substance selected from the group consisting of specific fats and non digestible oligosaccharides, associated with a microorganism, to a mammal for maintaining gut barrier homeostasis after a physical or psychological stress.

Claim 11 (currently amended): A method for inducing a pattern of gut barrier maturation similar to that observed with breast-feeding comprising the steps of administering a combination of a least one substance selected from the group consisting of fats, non-digestible oligosaccharides and combinations thereof, and at least one microorganism, to an infant inducing a pattern of gut barrier maturation similar to that observed with breast-feeding, wherein the combination comprises a polyamide or a polyamide precursor selected from the group consisting of spermidine, spermine, putrescine, cadaverine, ornithin, arginine and combinations thereof.

Claim 12 (withdrawn): The method according to claim 10, comprising the steps of administering sufficient composition to ensure an optimal barrier function in infants.

Claim 13 (withdrawn): The method according to claim 10, comprising the steps of administering sufficient composition to reduce the risk of the infant developing allergy and infection.

Claim 14 (cancelled):

Claim 15 (withdrawn): A composition according to claim 1, wherein the specific fats are selected from the group consisting of arachidonic acid (AA), docosahexanoic acid (DHA), and gangliosides contained in delactosed whey from buffalo milk.

Claim 16 (withdrawn): A composition according to claim 1, wherein the composition is in a form selected from the group consisting of a pharmaceutical, a food, and pet food composition.

Claim 17 (currently amended): The method according to claim 11 further comprising the step of ensuring ~~an~~ optimal barrier function in infants by administering the combination of at least one substance.

Claim 18 (currently amended): The method according to claim 11 further comprising the step of reducing the risk of developing allergy and infection by administering the combination of at least one substance.

Claim 19 (withdrawn): A method for producing a product intended for maintaining gut barrier homeostasis after physical or psychological stress comprising the steps of using a combination of at least one substance selected from the group consisting of specific fats or non digestible oligosaccharides, associated with a microorganism, for the preparation of the composition.

Claim 20 (withdrawn): A method for producing a product for inducing a pattern of gut barrier maturation similar to that observed with breast-feeding comprising the steps of using a combination of at least one substance selected from the group consisting of specific fats or non-digestible oligosaccharides, associated with a microorganism, for the preparation of the composition.

REMARKS

This Amendment is submitted in reply to the final Office Action mailed on April 17, 2009. A Petition to Revive the application is submitted herewith this Amendment. The Director is authorized to charge $1620.00 for the Petition to Revive and any additional fees that may be required, or to credit any overpayment to Deposit Account No. 02-1818. If such a withdrawal is made, please indicate the Attorney Docket No. 3712036-00694 on the account statement.

Claims 1-13 and 15-20 are pending in this application. Claims 1-10, 12-13, 15 and 19-20 were previously withdrawn. Claim 14 was previously canceled. In the Office Action, Claims 17-18 are rejected under 35 U.S.C. § 112. Claims 11 and 17-18 are rejected under 35 U.S.C. §102. In response, Claims 11 and 17-18 have been amended. The amendments do not add new matter and are supported in the specification at, for example, page 6, lines 1-6. In view of the amendments and/or for the reasons set forth below, Applicants respectfully submit that the rejections should be withdrawn.

In the Office Action, Claims 17-18 are rejected under 35 U.S.C. § 112, second paragraph as being indefinite for failing to point out and distinctly claim the subject matter which Applicants regard as the invention. Specifically, with respect to Claim 17, the Patent Office asserts that neither the claims nor the specification provides any means of accomplishing the "step" of " ensuring an optimal barrier function in infants." The Patent Office further states that "the use of the word 'an' implies there are multiple barrier functions and that only one needs to be optimized." See, Office Action, page 7, lines 10-21. Regarding Claim 18, the Patent Office alleges that neither the claims nor the specification provide any means of accomplishing the "step" of "reducing the risk of developing allergy and infection." See, Office Action, page 8, lines 14-16.

In contrast, however, Applicants respectfully submit that the specification describes how, during postnatal development, a newborn intestine experiences a process of maturation that ends by the establishment of a functional barrier to macromolecules and pathogenic bacteria. This phenomenon is called gut closure and appears to be affected by the newborn's diet. Hence, different studies with infants (JPGN, 1995, 21: 383-6) and animal models (Pediatr. Res., 1990, 28: 31-7) show that the maturation of the barrier is faster in breast-fed than in formula-fed newborns. This could explain the higher prevalence of allergy and infection in infants fed

formula than in those fed with mother milk. See, specification, page 1, lines 13-19. Further, the specification also clearly demonstrates that gut barrier function or gastrointestinal health in infants may be improved by providing specific bioactive ingredients combined with microorganisms that are able to deliver at least one of the ingredients all along the intestine. See, specification, page 3, lines 2-5. Moreover, the specification also clearly demonstrates, via Example 1, that rats who consumed compositions of the present invention were found to have restored intestinal permeability to normal levels after maternal separation, which increased the intestinal permeability to proteins and other macromolecules. See, specification, page 15, lines 2-4. This Example illustrates how the use of the compositions of the present invention work to ensure an optimal barrier function in infants (*e.g.*, rat pups). See, specification, Example 1.

Accordingly, in contrast to the Patent Office's assertion that Applicants have failed to address the rejection, Applicants respectfully submit that the specification is replete with disclosure indicating that administration of the compositions both "ensures" and "reduces," as required, in part, by Claims 17 and 18. Further, Applicants also note that the word "an" has been deleted from currently amended Claim 17.

Therefore, in view of the amendments and/or for at least the reasons set forth above, Applicants respectfully submit that the skilled artisan would immediately understand the scope of amended Claims 17-18 when read in view of the specification. Based on at least these noted reasons, Applicants believe that Claims 17-18 fully comply with the requirements of 35 U.S.C. §112, second paragraph.

Accordingly, Applicants respectfully request that the rejection of Claims 17-18 under 35 U.S.C. §112, second paragraph be reconsidered and withdrawn.

In the Office Action, Claims 11 and 17-18 are rejected under 35 U.S.C. § 102(b) as being anticipated by WO 01/64225 to Haschke et al. ("*Haschke*") and by WO 03/041512 to Giffard et al. ("*Giffard*"). Applicants respectfully submit that the cited references are deficient with respect to the present claims.

Currently amended independent Claim 11 recites, in part, a method for inducing a pattern of gut barrier maturation comprising the steps of administering a combination of a least one substance selected from the group consisting of fats, non-digestible oligosaccharides and combinations thereof, and at least one microorganism, to an infant, wherein the combination

comprises a polyamide or a polyamide precursor selected from the group consisting of spermidine, spermine, putrescine, cadaverine, ornithin, arginine and combinations thereof. The amendment does not add new matter. The amendment is supported in the specification at, for example, page 6, lines 1-6. During postnatal development, a newborn intestine experiences a process of maturation that ends by the establishment of a functional barrier to macromolecules and pathogenic bacteria (*i.e.*, gut closure). Different studies with infants and animal models show that the maturation of the barrier is faster in breast-fed than in formula-fed newborns, and could aid in explaining the higher prevalence of allergy and infection in infants fed formula than in those fed with mother milk. See, specification, page 1, lines 13-19.

An impressive number of different mechanisms integrate this barrier, mechanisms that act synergistically to protect the host from the luminal aggressions. The first barrier consists on the intestinal epithelium, a continuous monolayer of columnar epithelial cells sealed together by protein complexes, such as the tight junctions. The second is a non-specific barrier composed by mechanisms that protect the mucosal surface as saliva, gastric acidity, mucus layer, proteolytic digestion, alkaline intestinal pH, unstirred layer and intestinal peristalsis. The gut immune system (GALT) is able to respond selectively and specifically to the foreign molecules and pathogen microorganisms. Finally, and not less important, intestinal flora directly and indirectly protect against host invasion by pathogens and macromolecules with antigenic properties. See, specification, page 2, line 21-page 3, line 4.

In accordance with the present claims, Applicants have surprisingly found that gut barrier function or gastrointestinal health in infants may be improved by providing specific bioactive ingredients combined with microorganisms that are able to deliver at least one of the ingredients all along the intestine. See, specification, page 3, lines 2-5. The microorganisms of the present claims, which differ in their ability to survive in the different parts of the gastro-intestinal tract, can be incorporated into a cocktail. Thus, the bioactive ingredients can be added to the microorganism cocktail in order to reinforce their effects by stimulating the maturation of barrier mechanisms different to those stimulated by the microorganisms. See, specification, page 3, lines 11-17. The microorganism of the present invention are designed to release the beneficial substance(s) at a certain desired location of the gut and may be administered to a recipient, whereupon they will lyse at the respective location in the gut depending on the sort of

pretreatment undergone by the microorganism. See, specification, page 7, lines 11-28. The polyamines and/or polyamine precursors of currently amended Claim 11 also provide the advantage of substances that have the potential to favor intestinal cell differentiation. In contrast, Applicants respectfully submit that the cited references fail to disclose each and every limitation of the present claims.

For example, both *Haschke* and *Giffard* fail to disclose or suggest administering a composition comprising a least one substance selected from the group consisting of fats, non-digestible oligosaccharides and combinations thereof, and at least one microorganism, to an infant, wherein the combination comprises a polyamide or a polyamide precursor selected from the group consisting of spermidine, spermine, putrescine, cadaverine, ornithin, arginine and combinations thereof as is required, in part, by currently amended independent Claim 11.

Instead, *Haschke* is entirely directed toward a carbohydrate formulation, and method for administering same, for enhancing an immune response. The carbohydrate formulation includes, primarily, an effective amount of a prebiotic. See, *Hascke*, Abstract. Similarly, *Giffard* is entirely directed toward a foodstuff which comprises colostrum as a primary ingredient. The colostrums may be bovine, ovine or caprine. See, *Giffard*, Abstract, Claim 5. However, at no place in the disclosures do either *Haschke* or *Giffard* even suggest the use of a polyamide or a polyamide precursor, let alone a polyamide or a polyamide precursor selected from the group consisting of spermidine, spermine, putrescine, cadaverine, ornithin, arginine and combinations thereof as is required, in part, by currently amended independent Claim 11. As such, Applicants respectfully submit that *Haschke* and *Giffard* fail to disclose or suggest each and every element of the present claims.

Moreover, anticipation is a factual determination that "requires the presence in a single prior art disclosure of each and every element of a claimed invention." *Lewmar Marine, Inc. v. Barient, Inc.*, 827 F.2d 744, 747 (Fed. Cir. 1987) (emphasis added). Federal Circuit decisions have repeatedly emphasized the notion that anticipation cannot be found where less than all elements of a claimed invention are set forth in a reference. See, *e.g.*, *Transclean Corp. v. Bridgewood Services, Inc.*, 290 F.3d 1364, 1370 (Fed. Cir. 2002). As such, a reference must clearly disclose each and every limitation of the claimed invention before anticipation may be

found. For at least these reasons, Applicants respectfully submit that the cited references fail to anticipate the presently claimed subject matter.

Accordingly, Applicants respectfully request that the rejection of Claims 11 and 17-18 under 35 U.S.C. §102 be reconsidered and withdrawn.

For the foregoing reasons, Applicants respectfully request reconsideration of the above-identified patent application and earnestly solicit an early allowance of same. In the event there remains any impediment to allowance of the claims which could be clarified in a telephonic interview, the Examiner is respectfully requested to initiate such an interview with the undersigned.

Respectfully submitted,

K&L GATES LLP

BY _____

Robert M. Barrett
Reg. No. 30,142
Customer No.: 29157
Phone No. 312-807-4204

Dated: October 27, 2009